RESPONSE TO RESTRICTION REQUIREMENT

The Examiner required a restriction under 35 U.S.C. § 121, to one of three allegedly distinct invention. Specifically, the Examiner required Applicants to elect one of the following groups of claims for examination on the merits:

I. Claims 1-23, drawn to an emulsion or patch comprising an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant; classified in class 424, subclasses 401, 443 or 449, for example.

II. Claims 24-40, drawn to a method of treating pain comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant; classified in class 424, subclasses 401, 443 or 449, for example.

III. Claims 41-57, drawn to a method for inducing local anesthesia, comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant; classified in class 424, subclasses 401, 443 or 449, for example.

In response, Applicants respectfully traverse the restriction requirement and submit that, for the reasons provided below, the Examiner's restriction of the claims into Groups I, II, and III is improper.

The claims of Groups I , II, and III are directed toward compositions, patches comprising said compositions, and methods involving the use of said compositions and patches. Applicants submit that it a search of the subject matter of these three Groups would not be a serious burden on the Examiner, Indeed M.P.E.P. § 803 (Rev. 5, August 2006) provides:

> If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the

merits, even though they include claims to independent or distinct inventions.

Applicants respectfully submit that it would not be a serous burden for the Examiner to search the subject matter of Groups I, II, and III. Applicants respectfully submit that a search of the literature regarding the invention of Group II will, in fact, encompass the subject matter of Groups I and III as well. Accordingly, on this basis alone, Applicants respectfully request that the restriction requirement imposed under 35 U.S.C. § 121 be withdrawn and the subject matter of pending claims 1-57, be examined in one application.

Notwithstanding the above, in order to be fully compliant to the outstanding restriction requirement, Applicants hereby provisionally elect Group II, (claims 24-40), drawn to a method of treating pain comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant.

The Examiner has also required Applicants to elect a species of: (i) an antidepressant, (ii) NMDA receptor antagonist, (iii) lipophilic component, and (iv) surfactant. As required by the Examiner, Applicants hereby elect the following species:

(i) amitriptyline as the antidepressant (as recited in claim 31, as filed);
(ii) ketamine as the NMDA receptor antagonist (as recited in claim 36, as filed):
(iii) petrolatum as the lipophilic component (as recited in claim 16, as filed, and at p. 17, ll. 28 of the specification as filed); and
(iv) PEG-100 as the surfactant (as recited at p. 19, ll. 13-16, and in Tables 1 and 2 at pp. 31 and 33, respectively, of the application as filed).

The Restriction Requirement further provided that if Applicants elect an emulsion that further comprises a lipophilic intradermal penetration enhancer, then a further election of a single disclosed species of lipophilic intradermal penetration is required.

In response Applicants note that the recited emulsion may further comprise a lipophilic intradermal penetration enhancer. Accordingly, Applicants hereby elect transcutol P ® (Gattefossé (ethoxydiglycol)) as a single disclosed species of lipophilic intradermal penetration enhancer (page 21, line 15 of the application as filed).

The Restriction Requirement further provided that if Applicants elect an emulsion that further comprises a humectant, then a further election of a single disclosed species of humectant is required.

In response Applicants note that the recited emulsion may further comprise a humectant. Accordingly, Applicants hereby elect sorbitol as a single disclosed species of humectant (page 20, line 30 of the application as filed).

The Restriction Requirement further provided that if Applicants elect an emulsion that further comprises an antifoaming agent, then a further election of a single disclosed species of antifoaming agent is required.

In response Applicants note that the recited emulsion may further comprise an antifoaming agent. Accordingly, Applicants hereby elect simethicone as a single disclosed species of antifoaming agent (page 20, line 20 of the application as filed).

Claims 24-40 of elected Group II read on each of the above-elected species of (i) antidepressant, (ii) NMDA receptor antagonist, (iii) lipophilic component, (iv) surfactant, (v) lipophilic intradermal penetration enhancer, (vi) humectant, and (vii) antifoaming agent.

Applicants reserve the right to petition from the restriction requirement under 37 C.F.R. § 1.144. Applicants further reserve their right to file one or more divisional, continuation, or continuation-in-part applications directed to the subject matter recited by the non-elected claims, as well as to any other material disclosed in the specification that is not encompassed by the elected claims.